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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,793	01/11/2002	Victor Klimyuk	ICON-002	4086

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,793

Applicant(s)

KLIMYUK ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7072003</u> . | 6) <input type="checkbox"/> Other: _____ |

S.O.O.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claim 16 is withdrawn in light of the claim amendment.
3. The rejection of claims 1, 3-911, 13-16, 19-29, 36-42 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments or upon consideration of Applicants' arguments.

Claim Rejections - 35 USC § 112

4. Claims 2, 10, and 12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed December 3, 2004. Applicants traverse the rejection in the paper filed March 3, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Regarding the indefinite rejection of claim 2, Applicants argue that persons skilled in the art would understand the term "irradiation", and that the specification teaches irradiating protoplasts with gamma rays (response, paragraph bridging pages 9-10). However, exposing the protoplasts to fluorescent lights can also be called "irradiating." Is such irradiation encompassed by the claims, for example? That the specification mentions gamma radiation is acknowledged. However, limitations of the specification cannot be read into the claims.

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Regarding the indefinite rejection of claim 10, Applicants argue that, as disclosed in the specification on page 6, stable transformed lines may be obtained from a whole plant regenerated following transformation and selection (response, page 10, 1st full paragraph). However, limitation of the specification cannot be read into the claims. Claim 10 omits the step of making recombinant protoplasts from the regenerated plant.

Regarding claim 12: Applicants argue that persons skilled in the art would readily understand the term, particularly in light of the specification at pages 10-11 (response, page 10, 3rd full paragraph). However, the specification at pages 10-11 mentions recombination site separately from restriction sites, and even site-specific and homologous recombination. It therefore remains unclear how “recombination sites” is distinguished from these other sites.

5. Claims 20-35 and 42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed December 3, 2004. Applicants traverse the rejection in the paper filed March 3, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the claimed products have in common a chromosome fragment, or regarding the products of claims 30-35, fragments that exhibit normal plant chromosomal activities (response, page 11, 1st full paragraph). However, each specie of the claimed genus will not share the same chromosome fragments. The chromosome fragments also will not share the

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same functions, as each will carry different sets of genes, which will confer different properties to the host cells, seeds, and plants. Applicants argue that they are not relying on the disclosure of the method of making the products to provide the requisite support for the claimed products, and direct attention to Examples 1-3 of the specification as providing the necessary written description support (response, page 11, 1st full paragraph). However, these products disclosed in those examples are not representative of the entire genus of recombinant nucleic acids, protoplasts, cells, plants and seeds encompassed by the claims, as other recombinant nucleic acid, protoplasts, cells, plants, and seeds would have different structures and functions.

6. Claims 1-16 and 18-42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making plant protoplasts or cells or hybrid plant species comprising a plant artificial chromosome by irradiating protoplasts with gamma radiation, does not reasonably provide enablement for the claimed methods by producing chromosome fragments in any other manner, or by producing chromosome fragments in whole plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed December 3, 2004. Applicants traverse the rejection in the paper filed March 3, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue, regarding the issue that the specification does not enable fragmentation of chromosomes in plant protoplasts other than by treatment with gamma irradiation, that irradiation and treatment with chemicals is explicitly disclosed on page 7 of the specification.

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Applicants argue that four prior art references are cited, and cite two others in their remarks (response, page 12, 1st full paragraph). However, copies of those references are not provided.

Regarding the issue that the specification does not enable the method of making plants comprising plant artificial chromosomes wherein chromosome fragments are produced within plants, Applicants argue that page 7 of the specification discloses that protoplast fusion or crossing following irradiation revitalizes or revives the protoplast/plant containing the fragmented chromosomes (response, paragraph bridging pages 12-13). However, the specification does not show that a whole plant survives the radiation, such that it can still be crossed. The comment on page 7, regarding fusing protoplasts to revive the transformed, treated protoplasts, does not mention anything about whole plants.

Regarding claims 30-35 and 42, Applicants argue that pages 5-6 of the specification teaches which chromosomal elements are important in order for a chromosomal fragment to exhibit normal plant chromosomal activities (response, page 13, 1st full paragraph). However, this does not teach how one skilled in the art is to use the claimed recombinant nucleic acids. The properties conferred to host cells that comprise the recombinant nucleic acids are not dependent on the centromeric sequences. Applicants also argue, regarding claim 33, that the claimed nucleic acids are recited in terms of cell types in which they are functional (response, page 13, 1st full paragraph). However, claim 33 broadly encompasses all cell types. If the recombinant nucleic acid is only functional in plant and yeast cells, as Applicants appear to be admitting, then it is suggested that claim 33 be amended by indicating that the cell is a plant or yeast cell.

Claim Rejections - 35 USC § 103

7. Claims 1, 2, 5-16, and 18-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Famelaer et al. (Theor. Appl. Genet., 1990, Vol. 79, pages 513-520) in combination with Blume et al. (Plant Journal, 1997, Vol. 12, pages 731-746) and Adam et al. (Plant J., 1997, Vol. 11, pages 1349-1358), for the reasons of record stated in the Office action mailed December 3, 2004. Applicants traverse the rejection in the paper filed March 3, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue Famelaer does not teach the transformation of protoplasts with an exogenous nucleic acid before chromosome fragmentation (response, page 14, 1st full paragraph). However, Applicants are addressing Famelaer et al. in isolation, rather than considering the references in combination when making this argument. Applicants criticize the teachings of Famelaer et al. by arguing that they had problems with unstable transmission rates with first and second generation progeny and saw a decrease in transmission rates when first generation progeny were fertile (response, page 14, 1st full paragraph). However, fertile hybrid plants were also obtained, and progeny analysis revealed a normalization of the transmission rate. Further, the instant claims do not mention anything concerning transmission rates or second generation plants.

Applicants also argue that Blume et al. only teach plant transformation methodologies, that Adam et al. teach use of YAC vectors in stably transformed plant cells, and that the references do not supply the deficiencies of Famelaer et al. Applicants argue that the secondary references do not teach or suggest modifying the methods of Famelaer et al. (response, page 14, 2nd full paragraph and page 15, 1st full paragraph). However, it is not necessary that a reference

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actually suggest changes that Applicants made. See *In re Sheckler*, 438 F.2d 999, 1001, 168 USPQ 716, 717 (CCPA 1971). The difference between claim 1 and Famelaer et al. is the presence of transgenic material. Applicants do not provide any reasons why plant artificial chromosomes or hybrid plants cannot be made from transgenic plants using the method of Famelaer et al., simply because of the presence of exogenous nucleic acid in the genome. The exogenous nucleic acid does not change the treatment of chromosomes, protoplasts, plants, seeds, or any step in the method of Famelaer et al. in any manner. The only difference is the presence of exogenous nucleic acid in the genome of the starting material. One of ordinary skill in the art would not have any less of an expectation of success. Similarly, using the method of Famelaer et al. with plants comprising YACs does not affect change the method steps of Famelaer et al., and the expectation of success of the method does not change.

Summary

8. Claims 1-16 and 18-42 remain rejected.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 25, 2005



Ashwin D. Mehta, Ph.D.
Primary Examiner
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